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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,834	12/20/2001	Ralph Lipp	SCH-1859	1489

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,834	LIPP ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment and Response filed 11/12/03.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Schollkopf et al (USPN 5,827,842 hereafter '842), Li (WO 96/40087 hereafter '087), Lipp et al (USPN 5,676,968 hereafter '968) and Hansen et al (USPN 5,120,546 hereafter '546). The claims are drawn to a transdermal delivery system for delivering gestagens. The matrix of the transdermal delivery system is a polyacrylate adhesive, comprising copolymers of various acrylic monomers such as hydroxyethylacrylate and 2-ethylhexylacrylate. The matrix further comprises β-cyclodextrin as a crystallization inhibitor. The matrix also comprises penetration enhancer as lauryl alcohol, and methyl esters.

4. '842 discloses a potent gestagen (example 26 and 27). The reference discloses (21S)-21 -hydroxy-21-methyl-14,17-ethano-19-norpregna-4,9-diene-3,20-dione, and suggests that the compound can be formulated into transdermal preparations (col. 6, lin. 29 – 31). The invention

does not specify the type of transdermal matrix that is useful, yet any transdermal device would comprise an adhesive component.

5. '087 teaches a transdermal delivery system where the matrix is a polyacrylate adhesive. The matrix is a copolymer of 2-ethylhexylacrylate and hydroxyhexylacrylate and further comprises estradiol and other gestagens (pg. 3, lin. 15 – pg. 4, lin. 12; examples). The reference however is silent to other components found common in the art, components such as stabilizers and penetration enhancers. These components are well known in the art, and would be incorporated in to any transdermal composition to improve the stability, performance and drug delivery of the formulation.

As seen in '968, which teaches a transdermal delivery of drugs, the formulation comprises stabilizers (crystallization inhibitors) such as N-vinylpyrrolidone products and derivatives like Kollidon® and dextrins such as β-cyclodextrin. The matrix of the reference is a polyacrylate adhesive that incorporates penetration enhancers such as lauryl alcohol, glycerol and urea (col. 2, lin. 4 – 67, examples).

'546 discloses a transdermal formulation comprising polyacrylate as the matrix material, lecithin as a penetration enhancer (col. 8, lin. 29 – 38), and estradiol as an active agent (col. 6, lin. 38 – 43). A skilled artisan would have been motivated to use the lecithin of '546 in order to improve the delivery f the gestagen in the combination. Also the formulation of '546 comprises many of the same components as '968 and '087, specifically polyacrylate matrices, with similar penetration enhancers delivering estradiols.

With regard to claim 11, which recites concentrations for the potent gestagen of the transdermal system, it is the position of the examiner that this concentration does not impart

patentability on the claimed invention. The concentration recited a concentration that can be determined through routine experimentation. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various transdermal compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With regard to claim 16 that discloses the estrogen as estradiol-3,17-betadiproprionate, it is the position of the examiner that this limitation does not impart patentability on the claimed invention since the compound of the invention and those of the presented are chemical analogues. '546 discloses the use of estradiol –3,17-diacetate as a drug in the composition (col. 7, lin. 59 – 61). Estradiol-3,17-diacetate is a similar composition (differing only by two methyl groups) and is used for the same purpose in a similar matrix environment. It would be obvious to substitute the two compounds since they perform the same function, are derived from the same source and are delivered through a similar if not identical environment.

With these things in mind it would have been obvious to one of ordinary skill in the art to combine the teachings of and suggestions of the art. A skilled artisan would have combined the crystallization inhibitors of '968 with the matrix of '087 in order to reduce crystallization and

improve delivery. '968 and '087 both comprise polyacrylate matrices, and a skilled artisan would expect the combination to be successful. The skilled artisan would have been motivated to include the permeation enhancers and active agents (estradiol-3,17-diacetate) of '546 in order to better deliver the composition through the skin. A skilled artisan would have been motivated to follow the suggestion of the art in order to optimize and maximize the delivery of the active agents. A skilled artisan would have followed the suggestions of '842 to deliver the potent gestagen of the invention transdermally, and included the gestagen in a combination of '968 and '087 in order to provide a transdermal with better cohesive strength that delivered gestagens better. From this combination it would have been expected to achieve a structurally cohesive transdermal delivering potent gestagens.

Response to Arguments

6. Applicant's arguments filed 11/12/03 have been fully considered but they are not persuasive. Applicant argues that:

a. The prior art combination provides no motivation to combine the potent gestans of '842 with the transdermal matrix of ''087, '968, and '546.

b. The invention produces unique properties to that of the combination.

7. Regarding argument a., '842 establishes that the compounds can be used in a transdermal device, while '087 describes such a device is capable of delivering various hormone derivatives including those within the same class as the compounds of '842. The formulation of '842 is known in the art to be advantageous for hormone delivery and would provide improved support and delivery. A skilled artisan would be motivated to deliver the hormones of '842 via the

transdermal formulation of '087. '968 and '546 are used to further include the further components, which would improve the delivery such as crystallization inhibitors and other stabilizing compounds. It is the position of the examiner that since polyacrylate matrices are well known for the delivery and support of sex hormones, and it has been established that potent gestans can be delivered transdermally, it is not patentably distinct to simply deliver very potent hormones in a well-known delivery method.

8. Regarding b., applicant cites improvements to the transdermal device yet does not claim them. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., improved transdermal flow) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). These features appear to be the basis for patentability, and should be placed into the claims to more clearly distinguish from the prior art. Barring their inclusion, the claims remain obviated by the prior art.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
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MP Young

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